4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2020-N-0861]**

# Phillip R. Carawan: Final Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act ) debarring Phillip R. Carawan for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Carawan was convicted, as defined in the FD&C Act, of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Carawan was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of June 13, 2020 (30 days after receipt of the notice), Mr. Carawan has not responded. Mr. Carawan's failure to respond and request a hearing constitutes a waiver of Mr. Carawan's right to a hearing concerning this matter.

**DATES:** This order is applicable **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Jaime Espinosa (ELEM-4029) Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743 or at debarments@fda.hhs.gov .

**SUPPLEMENTARY INFORMATION**

## I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On January 9, 2020, Mr. Carawan was convicted as defined in section 306(*l*)(1)(B) of the FD&C Act, in the U.S. District Court for the Eastern District of North Carolina, when the court accepted Mr. Carawan's plea of guilty and entered judgment against him for the offense of violating the Lacey Act and Aiding and Abetting. This offense was in violation of 16 U.S.C. 3372(d)(1) and 3373(d)(3)(A)(j) and 18 U.S.C. 2.

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: as contained in the Indictment, filed on June 26, 2019, Mr. Carawan served as the owner and operator, and acted as the President and Chief Executive Officer, of Capt. Neill's Seafood, Inc. (Capt. Neill's). Capt. Neill's is a North Carolina corporation in the business of purchasing, processing, packaging, transporting, and selling seafood and seafood products, including crab meat from domestically harvested Atlantic blue crab, and products made from Atlantic blue crab. From as early as

January 1, 2012 and continuing through December 31, 2015, Mr. Carawan caused Capt. Neill's to purchase foreign crab meat from South American and Asia. Mr. Carawan directed Capt. Neill's employees to repackage the foreign crab meat into containers labeled "Product of USA." Mr. Carawan then knowingly caused those containers of foreign crab meat to be sold as jumbo domestically harvested blue crab to customers. During the relevant time frame, Mr. Carawan caused the sale of approximately 200,536 pounds of crab meat falsely labeled "Product of USA" with a total retail market value of $4,082,841.

As a result of this conviction FDA sent Mr. Carawan, by certified mail on May 6, 2020, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Carawan's felony conviction of violating the Lacey Act and Aiding and Abetting in violation of 16 U.S.C. 3372(d)(1) and 3373(d)(3)(A)(j) and 18 U.S.C 2, constitutes conduct relating to the importation into the United States of an article of food because the offense involved Mr. Carawan aiding and abetting the importation of foreign crab meat to be falsely labeled as "Product of USA."

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Carawan should be subject to a 5-year period of debarment. The proposal also offered Mr. Carawan an opportunity to request a hearing, providing Mr. Carawan 30 days from the date of receipt of the letter in which to file the request, and advised Mr. Carawan that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Carawan failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR Part 12).

## II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Carawan has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Carawan is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Phillip R. Carawan is a prohibited act.

Any application by Mr. Carawan for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2020-N-0861 and sent to the Dockets Management Staff (see ADDRESSSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket, and will be viewable at https://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m. Eastern time, Monday through Friday.

Dated: October 19, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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